IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

BRUCE N. SAFFRAN, M.D., PH.D., Plaintiff,	§	
v.	§	
	§	CIVIL ACTION NO. 2:07-CV-451 (TJW)
JOHNSON & JOHNSON and CORDIS CORPORATION, Defendants.	§	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

Pending before the Court is defendants Johnson & Johnson ("J&J) and Cordis Corporation's ("Cordis") (collectively "Defendants") motion for judgment as a matter of law ("JMOL"). (Dkt. No. 296.) Defendants seek JMOL that (1) there is no infringement; (2) the patent-in-suit is invalid; (3) there is no willful infringement; and (4) there was not sufficient evidence to support $482,000,000.00 in damages. The motion is GRANTED-in-part and DENIED-in-part. The Court DENIES Defendants' motion for JMOL on the issues of infringement, validity, and damages because the Court concludes that sufficient evidence supports the jury's verdict on these issues. The Court, however, GRANTS Defendants' motion for JMOL on the issue of willful infringement because the Court holds, as a matter of law, that there was no willful infringement.

II. FACTUAL AND PROCEDURAL BACKGROUND

On January 12, 2011, a jury trial commenced in this case. Plaintiff Dr. Bruce Saffran claimed that Defendants directly and willfully infringed U.S. Patent No. 5,653,760 ("the '760

Patent") by the Defendants' Cypher products and their use.[1] Defendants denied that they directly and willfully infringed the '760 Patent, and the Defendants further claimed that the '760 Patent is invalid because it is obvious under 35 U.S.C. § 103. On January 28, 2011, the case was submitted to the jury, and the jury returned a verdict finding that the '760 Patent is valid and that Defendants had directly and willfully infringed the patent by the use of their Cypher products. The jury found the amount of damages to be $482,000,000.00.

III. LEGAL STANDARD

JMOL may be granted only if "the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [an] issue." Fed. R. Civ. P. 50(a)(1). A motion for JMOL is a procedural issue not unique to patent law; thus, such motions are reviewed under the law of the regional circuit. *Summit Tech., Inc. v. Nidek Co.*, 363 F.3d 1219, 1223 (Fed. Cir. 2004). In the Fifth Circuit, JMOL may not be granted unless "there is no legally sufficient evidentiary basis for a reasonable jury to find as the jury did." *Hiltgen v. Sumrall*, 47 F.3d 695, 700 (5th Cir. 1995) (internal citation omitted). The court reviews all the evidence in the record and must draw all reasonable inferences in favor of the nonmoving party; however, a court may not make credibility determinations or weigh the evidence, as those are solely functions of the jury. *See Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).

[1] The asserted claims of the '760 Patent were 1-3, 6, 8, 9, 11, 13, 15, 17 and 18. The Defendants' Cypher products include stents marketed under the Cypher brand names, including Cypher, Cypher Select, and Cypher Select Plus. The parties stipulated that "[t]here are no relevant material differences between the different versions of Cypher stents. Defendants will not present additional non-infringement defenses based upon differences among the various Cypher stents. If one Cypher stent is deemed to infringe any apparatus claim, then all Cypher stents are deemed to so infringe that apparatus claim. If one Cypher stent is deemed to infringe any method claim when practiced in the United States, then all Cypher stents are deemed to so infringe that method claim practiced in the United States. No party shall refer to the difference in the Cypher stents." (Dkt. No. 278, Section E(1)(a).)

Defendants approached the Court at Plaintiff's case-in-chief and at the close of evidence regarding their intention to file their JMOLs. (*See* 1/25 PM Tr., 167:8-20; 1/27 PM Tr., 146:17-148:10.) The Court instructed the parties both times that they were to file their JMOL in writing after trial and it would be deemed timely whenever it was filed. (*See id*.) The Court allowed this because in order to preserve the right to file a post-trial Rule 50(b) motion, the moving party must first request JMOL at the close of evidence. *Taylor Pub. Co. v. Jostens, Inc.*, 216 F.3d 465, 471 (5th Cir. 2000).

IV. DISCUSSION

A. Reconsideration of Claim Construction Rulings

Before ruling on its motion for JMOL, Defendants ask the Court to revisit several of its claims construction rulings. Defendants ask the Court to reconsider its construction for the terms "layer," "device," and the "material release means." (Mot. for JMOL, Dkt. No. 296, at 11-12.) The Court, however, DENIES Defendants' motion for reconsideration and maintains the claim construction rulings as set forth in its September 20, 2010 Claim Construction Order. (*See* Dkt. No. 111.)

Defendants also ask the Court to reconsider its clarification of the construction of "layer" that the Court explained in its *Daubert* ruling (Dkt. No. 277) and its Order denying summary judgment (Dkt. No. 279). (*See* Mot. for JMOL, Dkt. No. 296, at 12.) As the Court explained in its Claim Construction Order, the term "layer" is construed as "a single layer" because of the disclaimers by the patentee. (Dkt. No. 111.) The Claim Construction Order further explained that because the relevant claims in the '760 Patent use the "comprising" transitional phrase, the plaintiff would be able to take advantage of that open-ended phrase. (*Id.* at 19-20.) But the Court also warned the plaintiff not to attempt to use the "comprising" language to get around the

Court's claim construction holding that "layer" was limited to a single layer. (*Id.* at 20.) This distinction is relevant in this case because it is undisputed that the Cypher stent has two layers: (1) the Parylene C layer and (2) the drug eluting layer. (*See* Dkt. No. 279, at 4.) Although the parties dispute the function and operation of these layers, the parties do not dispute there are two layers on the stent. (*Id.*) Therefore, since the Court construed "layer" to mean "a single layer," the defendants argued and continue to argue that the Cypher stent does not infringe as a matter of law because it has two layers. (*See* Dkt. No. 296, at 12.) The Court disagreed with the defendants' argument in the Court's *Daubert* order and order denying summary judgment. (Dkt. Nos. 277 & 279.) As the Court held, because the "comprising" transitional phrase is used, "the Cypher stent may have more than one layer and still literally infringe as long as 'a single layer' of the Cypher stent can perform all of the 'layer' limitations" in a '760 Patent claim. (Dkt. No. 279, at 4.) The Court maintains its holding and DENIES Defendants' motion to reconsider this ruling.

B. Non-Infringement

Defendants argue that they are entitled to JMOL that they do not directly infringe any one of the asserted claims of the '760 Patent. (Dkt. No. 296, at 1-12.) Defendants argue there was no legally sufficient evidentiary basis for a reasonable jury to find that the Cypher stent meets five particular limitations in the '760 Patent claims. For the reasons discussed below, because the Court concludes that there was sufficient evidence for a reasonable jury to find that Cypher meets each of the five disputed limitations, the Court DENIES Defendants' motion for JMOL of no infringement.

1. Capable of Being Shaped in Three Dimensions by the Manipulation of Human Hands.

Each of the asserted claims of the '760 Patent require "a layer being capable of being shaped in three dimensions by manipulation by human hands." '760 Patent, 22:34-35. Defendants argue that there was not sufficient evidence at trial to find this limitation is met in the Cypher stent. (Dkt. No. 296, at 5.) At trial, Plaintiff's expert Dr. Freeman stated that the layer could be manipulated by human hands by virtue of its attachment to the stent. (1/24 AM Tr. 122:18-123:10.)[2] That is, Dr. Freeman showed how one could manipulate the stent in three dimensions by human hands, and then he stated that because the layer is attached to the stent, it naturally follows that one can manipulate the layer by human hands. (*Id.*) Defendants, therefore, argue that the "manipulation by human hands" limitation is not met because Defendants assume the limitation is a requirement that must be performed "independently" by the drug-eluting layer. (*See* Dkt. No. 296, at 3.)

The Court rejects Defendants' argument because a reasonable jury could have found that according to the plain and ordinary meaning of the claim terms as understood by one of ordinary skill in the art,[3] the layer need not be capable of *independently* being shaped by human hands. The Court observes that the defendants never asked the Court to construe the "manipulation by human hands" claim language as being an independent requirement for the layer. The proper time to raise this argument would have been during claim construction. Even so, the defendants never asked the Court to clarify its claim construction nor is it asking the Court to construe the phrase now.[4] Because the phrase was not construed, the jury was charged to give the words their

[2] In order to be consistent with the parties' briefs, all citations to the trial transcript, aside from citations to closing arguments and jury instructions, are cited to the date, AM or PM to designate morning or afternoon, and then the "page:line" in the transcript.

[3] For terms that were not construed by the Court, the jury was charged that "the other words of the claims have their plain and ordinary meaning as they would be understood by a person of ordinary skill in the art." (Trial Transcript, Jury Instructions, Dkt. No. 307, at 74:20-22.)

[4] The Court is not construing the "manipulation by human hands" limitation—particularly because the parties have failed to ask the Court to construe this phrase and there has been no

plain and ordinary meaning as understood by one with ordinary skill in the art. (Trial Transcript, Jury Instructions, Dkt. No. 307, at 74:20-22.) In doing so, a reasonable jury could have agreed with Dr. Freeman's testimony regarding the ability to manipulate the stent with human hands.

In addition, the defendants seek to imply that there must be "independent" manipulation of the layer by virtue of the Court's construction of "layer" as "a single layer." (Dkt. No. 296, at 2-5.) Defendants correctly state that the Court has required all limitations involving a "layer" to be performed by "a single layer." In accordance, Defendants argue that because this "layer" limitation requires both the additional Parylene C layer and the stent in order to be manipulated by human hands, there is no "single layer" that can perform the limitation. Defendants' argument, however, is based again on the same flawed assumption that the "single layer" must be capable of being manipulated by human hands. That the "layer" must be "a single layer" only changes the phrase to be read as "the [single layer] being capable of being shaped in three dimensions by manipulation by human hands." '760 Patent, 22:34-35. There is sufficient evidence to still find that the "single layer" is "capable" of being manipulated in three dimensions by human hands. The Court's construction of "layer" only requires that "a single layer" be "capable" of being shaped in three dimensions by human hands. There is a difference between something being "capable" of performing a limitation and "*independently* capable" of performing a limitation, and a reasonable jury could have found that the accused products performed the former limitation.

Therefore, the Court finds there was sufficient evidence to find that the single layer on Cypher is capable of being shaped in three dimensions by the manipulation of human hands.

2. The Layer is "Minimally Porous" to Macromolecules.

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briefing on the construction of this phrase. In any event, the Court observes that it would not necessarily read in the "independent manipulation" of the layer limitation that Defendants request.

Defendants argue that there was no legally sufficient evidentiary basis to find that the Cypher stent has the required limitation of a drug-eluting layer that is "minimally porous" to macromolecules. The Court has previously construed "minimally porous to macromolecules" to mean "substantially impermeable to macromolecules." (Dkt. No. 111, at 16-22.) It is undisputed that essentially all of the sirolimus (i.e., the drug) permeates out of the drug-eluting layer within ninety days. (*See* 1/24 PM Tr. 49:14-50:11 (Freeman).) The plaintiff's expert, Dr. Freeman, even admitted that the drug layer is "permeable." (*See id.* at 51:24-52:15.) Defendants, therefore, argue that "[i]t is simply impossible for the drug layer to be ***porous and permeable*** (as the proof shows and Saffran admits), and at the same time, ***substantially impermeable to sirolimus***, as Saffran contends." (Dkt. No. 296, at 7 (emphasis in original).)

The Court disagrees and holds that there was a legally sufficient evidentiary basis to find that the Cypher stent has the required limitation of a drug-eluting layer that is "minimally porous" to macromolecules. To illustrate, first, it is important to distinguish between "impermeable" and "*substantially* impermeable" (emphasis added)—the latter being the language used in the Court's construction. So when the plaintiff's witnesses admit that the layer is "permeable," that does not mean that the layer is not "*substantially* impermeable." Therefore, although the Defendants inquired whether the layer was "permeable" and "impermeable," (*see* 1/24 PM 51:24-52:15 (Freeman)) the real issue was whether the layer was "*substantially* impermeable" or not. Hence, according to the Court's claim construction, the issue is the degree of permeability—not an issue of whether it was absolutely impermeable. By considering the plain and ordinary meaning and based on the evidence and the language in the Court's claim construction, a reasonable jury may have found that the layer was "*substantially* impermeable" by believing the plaintiff's expert, Dr. Freeman, when he opined that because it takes such a long

time for the drug to release from such a thin layer, then it must be substantially impermeable. (*See* 1/27 PM Tr. 81:8-20 (Freeman) ("[The] layer is extremely thin, so thin that, you know, on the stent, you can't really see it with your eyes, and yet it holds on to that drug as it goes up through the artery and then releases it very, very slowly over periods of up to three months. It releases it over very periods of time out of a layer that is extremely thin.").) Consequently, in contrast to what Defendants argue, a reasonable jury may have found that it is entirely possible for the drug layer to be permeable to sirolimus while at the same time be *substantially* impermeable to sirolimus.

Indeed, a reasonable jury may have found Dr. Freeman's testimony on this issue more credible than the defendants' expert witness that opined on this issue—Dr. Atwood. Dr. Atwood admitted at trial that he had never heard of a "permeability coefficient." (1/27 AM Tr. 96:21-98:8 (Dr. Atwood).) At that point, a jury may have found that Dr. Atwood's arguments on this issue lacked credibility given that the Langer article (DTX-0021), which Dr. Atwood attempted to use to establish invalidity, explained that seemingly all non-porous membranes have a "permeability coefficient" that describes the partitioning and diffusion of molecules through a material. (*See* Langer Article, DTX-0021, at CSF00454993.) In addition, in the same paragraph that discusses the permeability coefficient, the Langer article states that "[t]he choice of biomaterial will determine membrane *permeability* and therefore *release rate* for each solute." (*Id.* (emphasis added).) Based on this evidence, which was particularly pointed out to the jury when Dr. Atwood was cross-examined on that very paragraph,[5] a reasonable jury may have determined that permeability is related to time given that this sentence states that permeability is related to the release rate. Once determining that permeability is partially a function of time, a

[5] (*See* 1/27 AM Tr. 100:7-101:4.)

reasonable jury could have determined that because it takes ninety days for the sirolimus to be released from the layer, then the layer is substantially impermeable to macromolecules.

Therefore, the Court finds there was sufficient evidence to find that the single layer on Cypher is minimally porous to macromolecules.

3. The Material Release Means Limitation

Defendants argue that there was no legally sufficient evidentiary basis to find that the Cypher stent has the required material release means limitation. (Dkt. No. 296, at 8.) Each of the asserted claims of the '760 Patent require "means for release of an at least one treating material in a [directional/unidirectional] manner when said layer is placed adjacent to a damaged tissue." (Dkt. No. 111, at 23-24.) The Court construed the function of this means-plus-function limitation as "to release a drug preferentially toward the damaged tissue." (Dkt. No. 111, at 24.) The corresponding structure was construed as "the chemical bond or linkage between the drug and the device." (Dkt. No. 277, at 10.)

There was sufficient evidence at trial for a reasonable jury to conclude that this means-plus-function limitation was met by the Cypher stent. Dr. Freeman testified that there was structure of hydrophobic bonds between the drug and the device. (1/24 AM Tr. 101:24-102:2 (Freeman).) Furthermore, Dr. Freeman testified that the above structure caused 90% of the drug to be released towards the damaged tissue, that is, the vessel wall. (1/24 AM Tr. 107:11-108:2; 136:11-137:1 (Freeman).) The jury may have found Dr. Freeman credible because Defendants' own witness, Dr. Falotico, appeared to support these specific opinions by Dr. Freeman. (*See* 1/26 PM Tr. 16:22-25 (Falotico) (stating that "the use of the hydrophobic polymer and the hydrophobic drug provide good control for the stent['s drug elution]").)

Defendants make two counterarguments. First, Defendants argue that "the undisputed evidence establishes that sirolimus has a natural target in cells – FKBP12." (Dkt. No. 296, at 8.) As Dr. Falotico stated, when the sirolimus is systemically delivered, it likewise seeks out the FKBP12 in the arterial wall and prevents restenosis. (*See* 1/26 AM Tr. at 91:23-94:22 (Falotico).) Therefore, Defendants argue that it is not the chemical bonds or linkages structure that causes the directional delivery, but instead Defendants argue that the directional delivery is a result of the natural properties of sirolimus and the vessel wall. As Defendants' counsel stated in closing, "[t]here's nothing in this coating that makes [the drug] go into the vessel wall; it goes into the vessel wall because that's its target. It does it when it's injected into pigs." (Trial Transcript, Closing Arguments, Dkt. No. 307, at 49:1-4.) The problem with Defendants' argument that sirolimus can get to the arterial wall on its own is that if the drug were injected into the body like it was with pigs, it also may have negative side effects. Defendants' own witness, Dr. Falatico, discussed that one side effect may be infection because sirolimus is an immunosuppressant that is also used for organ transplant patients. (1/26 PM Tr. 7:9-8:6.) As a result, Dr. Falatico agreed that it was the polymer layer on the stent that was "essential" and that the sirolimus "need[s] a way of controlling its release." (*Id.* at 14:5-17.) Dr. Falatico, the "father of Cypher," further stated that he would "let a polymer expert" answer questions regarding the details of the release from the polymer layer. (*Id.* at 17:2-14.) Hence, a reasonable jury may have relied on this and believed Dr. Freeman, a polymer chemist and polymer expert in this case,[6] when he opined, as discussed above, that the hydrophobic bonds provided the required structure for the function to release the drug preferentially toward the damaged tissue.

[6] Although Defendants' expert, Dr. Atwood, was also tendered as an expert in polymer chemistry and disagreed with Dr. Freeman, the jury may have found Dr. Freeman more credible given that Dr. Atwood, as discussed above, did not even know what a permeability coefficient is. (1/27 AM Tr. 96:21-98:8 (Dr. Atwood).) Indeed, Dr. Freeman was "shocked" that someone would not

Defendants' second counterargument is that Saffran's analysis of directionality at trial was based upon a legally improper identification of the two major surfaces recited in the claims. In claim 1 of the '760 Patent, for example, there are two limitations including "the first major surface of the layer being adapted to be placed adjacent to a damaged tissue" and "the second major surface of the layer being adapted to be placed opposite to the damaged tissue." '760 Patent, 22:36-39. Defendants claim that one major surface is the outer surface of the layer that faces away from the stent and that the second major surface is the inner surface that faces the Parylene C layer. Defendants, therefore, argue that it was improper for Saffran to assume that one major surface was on the outer surface of the stent and the other major surface was on the inside of the stent. Defendants argue these two surfaces described by Saffran are really the same surface. The Court, however, disagrees with Defendants and holds that there was sufficient evidence to find that one major surface was on the outer surface of the stent and the other major surface was on the inside of the stent. Similarly to the "manipulation by human hands" limitation above, Defendants are making an argument that could and should have been made during claim construction. Defendants have not asked the Court to construe either the "first major surface" limitation or the "second major surface" limitation. Hence, the jury was free to use the plain and ordinary meaning of the words as understood by one of ordinary skill in the art.[7] In doing so, a reasonable jury may have agreed with Dr. Freeman that in Cypher the surface that is facing the vessel wall is the first major surface and the second major surface is opposite the damaged tissue, which is inside the stent and facing the bloodstream. (1/24 AM Tr. 132:4-

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know what a permeability coefficient is if he was opining about permeation and polymers and claiming to be an expert in polymers. (1/27 PM Tr. 69:3-12 (Freeman.)

[7] As noted above, for terms that were not construed by the Court, the jury was charged that "the other words of the claims have their plain and ordinary meaning as they would be understood by a person of ordinary skill in the art." (Trial Transcript, Jury Instructions, Dkt. No. 307, at 74:20-22.)

133:7 (Freeman).) If a reasonable jury did so, it would have sufficient evidence to find infringement.

Therefore, based on the above analysis, the Court holds that there was a legally sufficient evidentiary basis for a reasonable jury to find that the Cypher stent has the required material release means limitation.

4. The "Device" Being Flexible in Three Dimensions by Manipulation of Human Hands

Each of the asserted claims requires a "device being flexible in three dimensions by manipulation of human hands." *See, e.g.*, '760 Patent, claim 1. This limitation is similar to the limitation discussed in Section IV(B)(1) above, that is, the limitation that the "layer being capable of being shaped in three dimensions by manipulation by human hands." *Id.* The only difference is that one limitation states "device" and the other states "layer," and additionally one recites "being capable of being shaped" and the other states "being flexible." *Id.* Defendants argue, for the same reasons as they argued in Section IV(B)(1) above, that none of the evidence demonstrates that that the drug-eluting layer by itself meets the claim limitation. The Court disagrees, however, for the same reasons discussed in Section IV(B)(1).

5. The Device Being Capable of Substantially Restricting the Through Passage of at least One Type of Macromolecule

Each of the asserted claims require a device "being capable of substantially restricting the through passage of at least one type of macromolecule." Defendants argue this limitation is not met in Cypher for the same reasons Defendants discussed in Section IV(B)(2) above. Likewise, the Court disagrees for the same reasons discussed in Section IV(B)(2).

C. Validity

Defendants also seek judgment as a matter of law that no reasonable jury could find that the asserted claims of the '760 Patent are valid. Defendants argue that each of the asserted claims of the '760 Patent is rendered obvious in light of (1) U.S. Patent No. 5,282,823 ("Schwartz"); (2) Schwartz in combination with U.S. Patent No. 5,545,208 ("Wolff"); and (3) Schwartz in combination with Langer, R.S. & Peppas, N.A., Present and Future Applications of Biomaterials in Controlled Drug Delivery Systems, Biomaterials 2:201-14 (1981) ("Langer").

The patents-in-suit are presumed valid and Defendants bore the burden of proof at trial to demonstrate obviousness by a preponderance of the evidence.[8] *Visto Corp. v. Seven Networks, Inc.*, Civ. No. 2:03-CV-333-TJW, 2006 WL 3741891, at *2 (E.D. Tex. Dec. 19, 2006). To overcome the jury's verdict, Defendants must establish that no reasonable jury could have failed to find invalidity. *Id.*

The Court holds that a reasonable jury could have failed to find that the '760 Patent was obvious. To begin with, Defendants bore the burden on this issue and the only evidence that Defendants presented at trial to show obviousness, besides the references themselves, was the testimony of their expert, Dr. Atwood. As already noted, there were reasons to doubt the credibility of Dr. Atwood—specifically for his obviousness opinion. This is because despite relying on the Langer reference as one of the three references for his obviousness opinion, as discussed above, Dr. Atwood admitted that he had never even heard of a permeability coefficient, which is discussed in Langer. Because Defendants had the burden of proof on this issue, a reasonable jury may have not believed Dr. Atwood's testimony on this issue and

[8] The parties agreed in this case that the burden will be preponderance of the evidence instead of clear and convincing evidence because the PTO did not have the opportunity to consider the prior art because it was not before the PTO. The parties reached this agreement due to a pending case in the Supreme Court that may potentially hold that in such situations the proper burden is preponderance of the evidence.

therefore decided that Defendants had not shown the '760 Patent was obvious—without even considering Saffran's evidence.

Saffran, however, did provide evidence that the '760 Patent was not obvious in light of Schwartz, Schwartz in combination with Langer, or Schwartz in combination with Wolff. First, Saffran's expert, Dr. Freeman, explained that the references (alone or in combination) did not disclose some of the limitations in all of the '760 Patent claims, such as the minimally porous limitation. (1/27 PM Tr. 60:8-21; 66:22-67:10; 69:23-70:5.) Additionally, Dr. Freeman explained that Langer and Wolff would not have been combined with Schwartz because of their teaching away from a combination with Schwartz. (*Id.* at 68:7-20; 70:11-24.) Finally, there was evidence presented in trial showing secondary indicia of non-obviousness relating to the claims of the '760 Patent. To illustrate one example, Dr. Anderson, the Defendants' witness, was asked at trial if it would "be fair to say that the solution to the problem that J&J presented to SurModics in connection with the development of the polymer layer for a drug-eluting stent was not an obvious one?" to which he replied that "[p]utting the whole package together was not obvious." (1/26 PM Tr. 78:24-79:4.) Hence, the Court holds that a reasonable jury could have failed to find that the '760 Patent was obvious and DENIES Defendants' motion for judgment as a matter of law on the grounds of invalidity.

D. Willful Infringement

Defendants seek JMOL that no reasonable jury could have found willful infringement in this case. Defendants argue that there was not sufficient evidence to find that there was an objectively high likelihood that Defendants' actions constituted infringement of a valid patent. For the following reasons, the Court finds that, as a matter of law, there was not an objectively high likelihood that Defendants' actions constituted infringement of a valid patent. Therefore,

the Court GRANTS Defendants' JMOL of no willful infringement. Because the Court finds that Saffran has not satisfied the objective prong of the willfulness inquiry, the Court need not address the second, subjective prong of *Seagate*.

The Federal Circuit has set forth a two-pronged approach to determining willful infringement. First, a patentee must make a showing of at least "objective recklessness." *In re Seagate Tech. LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (en banc). This first prong requires "clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent." *Id.* "The state of mind of the accused infringer is not relevant to this objective inquiry." *Id.* If the patentee can show objective recklessness, then the patentee must also prove the second prong by showing that the objectively-defined risk "was either known or so obvious that it should have been known to the accused infringer." *Id.* While the Federal Circuit did not set forth further guidance in *Seagate* for applying this test, it did indicate that the objectively-defined risk should be determined by the record developed in the infringement proceeding. *Id.* "The court's finding on willful infringement is one of fact, subject to the clearly erroneous standard of review." *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1374 (Fed. Cir. 2008) (internal citations omitted).

Defendants argue that the objective prong of *Seagate* has not been satisfied by Saffran because Defendants have presented credible invalidity and noninfringement defenses. Additionally, Defendants argue they presented reasonable claim construction arguments that would have been dispositive if adopted by this Court. Saffran argues there is clear and convincing evidence that Defendants met the objective prong of *Seagate*. Saffran argues he presented strong infringement arguments and Defendants did not present credible defenses.

The Court finds that the issues of infringement and validity were both hotly contested, close, and required an intensive factual inquiry. A reasonable jury could find for either party on the issues of validity and infringement in this case, and although that fact does not automatically immunize an accused infringer from a finding of willfulness, the record developed in this case shows that Defendants presented objectively reasonable and substantial defenses to infringement and validity. *Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1337 (Fed. Cir. 2009) ("While the fact that an issue was submitted to a jury does not automatically immunize an accused infringer from a finding of willful infringement, the record developed in the infringement proceeding in this case, viewed objectively, indisputably shows that the question of equivalence was a close one, particularly insofar as equivalence requires an intensely factual inquiry."). Further, the fact that certain facts were not presented to the jury, such as the close issue of claim construction,[9] does not preclude the court to consider them in its determination, as a matter of law, whether the first prong of *Seagate* is met. *See Cohesive,* 543 F.3d at 1374 (upholding district court's finding of no willful infringement where claim term was susceptible to a reasonable interpretation under which there would be no infringement). In this case, the issue of claim construction was close and Defendants' proposed interpretation for the claims, although eventually not adopted, was reasonable and based upon the specification and prosecution history of the '760 Patent. Thus, the Court takes the close issues of claim construction into consideration in its determination of whether Defendants' actions were "objectively reckless." *See id.*

[9] The Court is aware that the jury did not have the claim construction issues in front of them. The Court, however, takes judicial notice that the claim construction issues were closely contested, and the Court considers this evidence when deciding as a matter of law that there was no willful infringement.

The Court holds, as a matter of law, that there was not an objectively high likelihood that Defendants' actions constituted infringement of a valid patent. In other words, as a matter of law, Saffran has not proven by clear and convincing evidence that Defendants met the objective prong of *Seagate*. Therefore, the Court GRANTS Defendants' motion for JMOL of no willful infringement and directs the entry of judgment as a matter of law that Defendants did not willfully infringe the '760 Patent.

E. Damages

Defendants seek judgment as a matter of law that no reasonable jury could award Saffran $482,000,000 in damages. Defendants essentially argue that the licenses relied on by Saffran were improper and that the only proper licenses the jury should have relied on were Defendants' license agreements with Surmodics. Defendants, therefore, argue that by relying only on those license agreements, a reasonable jury could only find a reasonable royalty rate of 0.7% and not the 5.6% royalty awarded by the jury.

The amount of a prevailing party's damages in a patent case "is a finding of fact on which the plaintiff bears the burden of proof." *SmithKline Diag., Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991). To carry this burden, the patentee must sufficiently tie the expert testimony on damages to the facts of the case. *Uniloc USA, Inc. v. Microsoft Corp.*, --- F.3d ----, 2011 WL 9738, at *19 (Fed. Cir. Jan. 4, 2011). "[E]xpert testimony opining on a reasonable royalty rate must 'carefully tie proof of damages to the claimed invention's footprint in the market place." *Id.* at *21. Further, "there must be a basis in fact to associate the royalty rates used in prior licenses to the particular hypothetical negotiation at issue in this case." *Id.*

Plaintiff Saffran's damages expert, Mr. Ratliff, primarily relied on two licenses for his damages model: (1) a license between Cordis and Wyeth for the drug sirolimus; and (2) a license

agreement between MIVT and Endovasc for both a coating and a drug for treating restenosis. For the reasons below, both of these licenses were sufficiently comparable to be considered by Mr. Ratliff (and the jury) in determining a reasonable royalty rate. The Cordis-Wyeth license was sufficiently comparable because it was a license for Cordis to use the drug sirolumis, which is the drug used in Cypher. The '760 Patent covers a method of directional delivery that Cypher uses, at least in part, to deliver the drug sirolimus.[10] As Saffran established at trial, a drug like sirolimus is not very useful if it is not delivered to the damaged tissue. (*See* 1/24 PM Tr. 21:9-22:8 (Freeman); 1/26 PM Tr. 14:5-17 (Falotico).) Because the '760 Patent teaches the delivery mechanism and the Cordis-Wyeth license concerns the drug for the infringing product, Saffran and Defendants would have surely considered the Cordis-Wyeth license for sirolimus in their hypothetical negotiation. This is particularly true because Cordis was a party to the license and the license related to a technology to be used with the infringing product. It was also reasonable for Mr. Ratliff (and the jury) to rely on the license between Endovasc and MIVT, as it is sufficiently comparable. Plaintiff's witness Dr. Freeman discussed some of the similarities, and differences, between the technology underlying the Endovasc-MIVT license and the '760 Patent. Dr. Freeman stated that "they describe a drug-eluting coating for a stent. They use a single type of drug and one type of polymer in a very specific arrangement. (1/24 PM Tr. 22:18-20 (Freeman).) Dr. Ratliff, therefore, relied on the Endovasc-MIVT license because it was comparable, and he discussed the similarities and dissimilarities of the context of the Endovasc-MIVT license agreement with the hypothetical negotiation that would have taken place in this case. (1/25 PM Tr. 114:2-24 (Ratliff).)

[10] Once the jury is determining damages, it has already decided that Cypher infringes the '760 Patent. The '760 Patent claims cover, at least in part, a directional delivery method of delivering a drug to damaged tissue. Therefore, by the jury deciding infringement, it means practically that Cypher uses, at least in part, the technology covered by the '760 Patent to deliver the drug sirolimus to the damaged tissue.

For the reasons above, the Court disagrees with Defendants that the Surmodics license agreements were the only license agreements comparable to the technology in this case. Furthermore, there was sufficient evidence to find that the 1% royalty rate in the Surmodics license agreements was not very indicative of the proper reasonable royalty in this case. Plaintiff's expert, Mr. Ratliff, explained how the 1% royalty was a small part of the overall relationship between Surmodics and Cordis. Mr. Ratliff pointed out that, for example, "the agreements between SurModics and Johnson & Johnson basically had Johnson & Johnson paying SurModics' research fees, paying SurModics to actually make the coating for the stents or to assist Johnson & Johnson in doing so." (1/25 PM Tr. 111:11-15 (Ratliff).) A reasonable jury could determine, based on this and other similar evidence, that the 1% royalty was not a good baseline in this case because Saffran will not be being paid research fees and to manufacture the coating for the stents. A reasonable jury may conclude based on the evidence that the 1% royalty in the Surmodics agreements was much lower than it would have otherwise been, had it not been for the additional arrangements between Defendants and Surmodics.

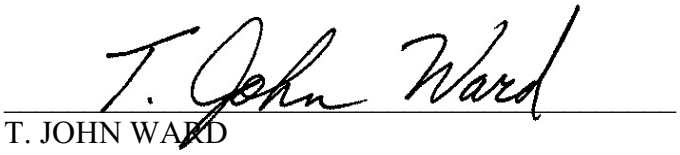
Therefore, a reasonable jury would have sufficient evidence to conclude that the 8% Endovasc-MIVT license and the approximately 7% Cordis-Wyeth license are better indicators regarding a reasonable royalty in this case, as opposed to the 1% Surmodics agreement. There is also the additional testimony by Mr. Ratliff regarding the application of the other *Georgia-Pacific* factors. (*See, e.g.*, 1/25 PM Tr. 85:4-95:7 (Ratliff).) This is sufficient evidence for a reasonable jury to find a reasonable royalty rate of approximately 5.6%. The fact that the Plaintiff was asking for 7% and the Defendants were asking for 0.7% and the jury found approximately 5.6% does not mean such a finding was not supported by substantial evidence. *See Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1212 (Fed. Cir. 2010) (discussing

how the jury was free to hear the expert testimony and decide for itself what to accept or reject). Given the baseline of 8.6 billion dollars and the jury finding an approximate 5.6% reasonable royalty, a reasonable jury had sufficient evidence to find damages of $482,000,000.00. The Defendants motion for judgment as a matter of law on this ground is DENIED.

V. CONCLUSION

Defendants' motion for JMOL is GRANTED-in-part and DENIED-in-part. The Court DENIES Defendants' motion for JMOL on the issues of infringement, validity, and damages because the Court concludes that sufficient evidence supports the jury's verdict on these issues. The Court, however, GRANTS Defendants' motion for JMOL on the issue of willful infringement because the Court holds, as a matter of law, that there was no willful infringement.

SIGNED this 31st day of March, 2011.



T. JOHN WARD
UNITED STATES DISTRICT JUDGE